1999

Daubert, Doctors and Differential Diagnosis: Treating Medical Causation Testimony as Evidence

Michael B. Kent Jr.
Campbell University School of Law, mkent@campbell.edu

Daubert, Doctors and Differential Diagnosis: Treating Medical Causation Testimony as Evidence

An assessment of admissibility is not the same as an assessment of sufficiency, but Daubert has created that confusion

By Michael B. Kent Jr.

CAROL HELLER began experiencing various respiratory problems shortly after Shaw Industries installed new carpeting in her house.[1] A few months later, she consulted an allergist, Dr. Joseph Papano. He took her medical and family histories, questioned her about the house's environment, ordered chest x-rays, and performed several laboratory tests. Based on his findings from the collected data, Dr. Papano ruled out various possible causes of Heller's respiratory problems. This winnowing process, known as "differential diagnosis" in the medical community, coupled with the close temporal relationship between Heller's symptoms and the installation of the new carpet, led Dr. Papano to conclude that the carpet was the cause of her illness.

Heller sued Shaw Industries for, among other things, failure to warn and defective design. She called Dr. Papano as an expert witness to testify on the issue of causation, but the trial court excluded his testimony. The problem: Although Dr. Papano conducted a differential diagnosis to determine what did not cause Heller's symptoms, he could point to no studies indicating that the carpet could cause them. Without this testimony, Heller could not prove causation, and the court granted summary judgment in favor of Shaw.

Michael B. Kent Jr. is a 1999 graduate of the University of Georgia Law School, having obtained his B.A. degree from the University of Alabama in 1995. Since writing this article, he has taken a position as law clerk for Judge J. Owen Forrester of the U.S. District Court for the Northern District of Georgia.

This is an edited and condensed version of the paper with which he won second place in the 1999 IADC Legal Writing Contest.

The Third Circuit, while disagreeing with some of the trial court's rationale, affirmed both the exclusion of Dr. Papano's testimony and summary disposition in favor of Shaw.

THE PROBLEM

The *Heller* case reveals one of the central problems underlying most mass and toxic tort litigation—proving that the defendant's product caused the plaintiff's injury. As is the case with other torts, the plaintiff in a mass or toxic tort case must show duty, negligence, causation and damage. In the mass or toxic tort context, however, the element of causation often plays a dispositive role. Plaintiffs must prove both that the product is capable of producing the injuries (general causation) and that the product actually did so (specific causation).[2] To do so, they must rely on the testimony of experts—toxicologists, engineers, physicians—with scientific and technical knowledge of the product in question and its effects on the human body. If the testimony of these experts is either inadmissible or insufficient to carry

1. Heller v. Shaw Indus. Inc., 167 F.3d 146 (3d Cir. 1999).

2. Wade-Greaux v. Whitehall Labs. Inc., 874 F.Supp. 1441, 1448 (D. V.I. 1994). *See also* Sterling v. Velsicol Chem. Corp., 855 F.2d 1188 (6th Cir. 1988) (discussing general and specific causation in mass tort class action litigation).

the burden of proof, plaintiffs' cases cannot go forward. Accordingly, the admissibility and sufficiency of the expert testimony often becomes a hotly contested issue.

Inherent in ruling on the admissibility of expert testimony is that courts must review the underlying science to determine the reliability and relevance of the evidence. For 70 years, the "general acceptance" test from *Frye v. United States*[3] enjoyed almost uniform application in both state and federal courts.[4] This test admitted scientific evidence if, and only if, it was generally accepted in the pertinent scientific community. Under *Frye*, courts looked deferentially to scientists in determining whether the proffered evidence met the standards of scientific reliability.

This era of deference came to an end with the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals Inc.*,[5] which interpreted Federal Rule of Evidence 702 as superseding the common law "general acceptance" test. The Court read Rule 702 as establishing a system wherein federal trial judges ensure the reliability, as well as the relevance, of scientific testimony.

Trial judges must serve as "gatekeepers" when it comes to scientific evidence, assessing the methodologies underlying the testimony of expert witnesses. Trial judges must review and screen evidence based on everything from aerodynamics to epidemiology. The "gatekeeper" role was reaffirmed in *General Electric Co. v. Joiner*[6] and *Kumho Tire Co. v. Carmichael.*[7]

A source of scientific evidence in mass and toxic tort litigation is the medical technique called differential diagnosis. It is a clinical procedure whereby medical doctors determine which of several potential diseases is causing the patient's symptoms by ruling out possible causes until only one or two remain.[8]

Several courts have recognized the significance of this procedure to the causation issue.[9] The problem thus turns on the reliability and fit of using the technique to determine cause in the legal, rather than the clinical, sense. Although the cases have fleshed out many of the questions concerning the use of differential diagnosis as evidence of causation, the answers to these questions remain somewhat vague because courts often confuse general and specific causation, as well as admissibility and sufficiency. A clear treatment of the issue is needed.

DIFFERENTIAL DIAGNOSIS

Differential diagnosis, as used in the medical profession, is a clinical process whereby doctors determine from what disease a patient suffers. By comparing the patient's symptoms to symptoms associated with known diseases, the physician attempts to identify the disease or diseases that best explain the facts of the patient's case.[10] Identification takes place through a process of elimination,[11] with the physician collecting data on the patient's history and illness, analyzing that data and ruling out various diseases until a final diagnosis is reached. In short, differential diagnosis is

3. 293 F. 1013, 1014 (D.C. Cir. 1923).

4. *See* CHRISTOPER B. MUELLER & LAIRD C. KIRKPATRICK, EVIDENCE § 7.8, at 744 (1995).

5. 509 U.S. 579 (1993).

6. 522 U.S. 136 (1997).

7. 119 S.Ct. 1167 (1999), *rev'g* 131 F.3d 1433 (11th Cir. 1997). For district court decision, see Carmichael v. Samyang Tires Inc., 923 F.Supp. 1514 (S.D. Ala. 1996).

8. STEDMAN'S MEDICAL DICTIONARY 389 (5th ed. 1982).

9. *See, e.g.*, In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 758 (3d Cir. 1994) (recognizing differential diagnosis as technique that involves assessing causation with respect to particular individual); Cavallo v. Star Enter., 892 F.Supp. 756, 771 (E.D. Va. 1995) (acknowledging importance of differential diagnosis to question of specific causation), *aff'd in relevant part,* 100 F.3d 1150 (4th Cir. 1996).

10. Whiting v. Boston Edison Co., 891 F.Supp. 12, 21 n.41 (D. Mass. 1995). *See also* A. MCGEHEE HARVEY & JAMES BORDLEY III, DIFFERENTIAL DIAGNOSIS 7 (2d ed. 1970).

11. In re Breast Implant Litig., 11 F. Supp.2d 1217, 1229 (D. Colo. 1998).

the act of distinguishing one disease from another to select a proper treatment.[12]

It thus aids a physician in determining the injury from which a person suffers, but the technique also is presented as evidence of causation at trial. This has drawn criticism from courts and commentators alike.[13] This criticism often is justified because, while physicians speak in terms of "cause," they generally focus their differential diagnosis on defining the patient's illness.[14]

On the other hand, a thorough diagnosis frequently considers the underlying causal agents of a disease in prescribing a treatment.[15] Indeed, some courts describe the technique of differential diagnosis as "differential etiology," a term that heavily stresses the causation issue since etiology is the science and study of the causes of disease.[16]

When physicians seek to determine the disease causing the symptoms—for example, lung cancer—they often look for and rule out known etiologic agents of the disease—for example, asbestos. The most likely agent remaining after this sifting is considered the cause of the disease. If no known etiologic agents remain on the list, attention is focused on any suspicious substances, such as chemical compounds, to which the patient has been exposed. For treatment purposes, one or more of these substances is presumed to be the cause of the patient's disease.[17]

Therefore, differential diagnosis often consists of a clinical determination, by process of elimination, of both the disease causing the patient's symptoms and the most likely etiologic agent causing that disease. The problem arises from extrapolating from this determination of clinical causation, for treatment purposes, to causation in the legal sense.

Because physicians utilize differential diagnosis in a clinical setting, some lawyers contend that it does not constitute science.[18] Medical writers, however, indicate the contrary, noting that a physician should perform a differential diagnosis in the same manner as other scientific research—objectively collecting all the facts, analyzing them in an unprejudiced fashion and ending with a logical conclusion.[19]

Certainly, the steps in conducting a proper differential diagnosis resemble the scientific method, and differential diagnosis remains scientific in nature although performed in a clinical environment. Accordingly, the Supreme Court's decision in

---

12. *See* Stuart F. Spicker, *Ethics in Diagnosis: Bodily Integrity, Truth-telling, and the Good Physician, in* THE ETHICS OF DIAGNOSIS 107, 108 (José Luis Peset & Diego Garcia eds., 1992) (identifying treatment as final step in process of clinical reasoning).

13. *See, e.g.*, Lofgren v. Motorola, 1998 WL 299915, at *24 (Ariz. Super. Ct. June 1, 1998) (finding, under *Frye* standard, that differential diagnosis is "unequivocally rejected by the scientific community" as means of determining causation); Bruce R. Parker, *Understanding Epidemiology and Its Use in Drug and Medical Device Litigation,* 65 DEF. COUNS. J. 35, 57 (1998) (stating that differential diagnosis does not generally require doctor to form conclusions regarding causal agents).

14. *See, e.g.*, ROBERT H. SELLER, DIFFERENTIAL DIAGNOSIS OF COMMON COMPLAINTS 294-97 (3d ed. 1996) (listing "causes" of shortness of breath as, *inter alia,* asthma, emphysema, chronic bronchitis, and congestive heart failure).

15. MYRON R. SCHOENFELD, STRICTLY CONFIDENTIAL: HOW DOCTORS MAKE DECISIONS 65 (1990).

16. *See, e.g.*, McCullock v. H.B. Fuller Co., 61 F.3d 1038, 1044 (2d Cir. 1995).

17. Not all physicians agree on the soundness of presuming causation. *See, e.g.*, Barrow v. Bristol-Myers Squibb Co., 1998 WL 812318 at *23 n.221 (M.D. Fla. Oct. 29, 1998) ("Dr. Kotzin was critical of those who contend that silicone gel breast implants are a cause of symptoms because they cannot explain such symptoms using differential diagnosis.").

18. *See* Petition for Writ of Certiorari at 11-12, Moore v. Ashland Chem. Inc., 151 F.3d 269 (5th Cir. 1998) (en banc), filed in the U.S. Supreme Court January 5, 1999 (No. 98-992) (arguing that *Daubert* should not apply to clinical medical causation testimony because it is based on technical skill and experience rather than scientific knowledge). The Supreme Court's decision in *Kumho Tire* (footnote 7) may have rendered this argument moot because the Court held that *Daubert*'s gatekeeper obligation applies not only to expert testimony based on science, but to all expert testimony.

19. HARVEY & BORDLEY, *supra* note 10, at 3.

Daubert applies to its use as causation evidence in federal trials.

DAUBERT AND JOINER

A. Daubert

Daubert is the seminal case regarding the admissibility of scientific expert testimony. The new system it instituted for testing the admissibility of scientific evidence has resulted in confusion among commentators and the lower courts.[20]

The Court held that Rule 702 of the Federal Rules of Evidence supersedes the common law *Frye* test of general acceptance in the relevant scientific field. The Court first noted that the Federal Rules render a broad range of evidence admissible and that neither Rule 702 nor its legislative history mentions "general acceptance." The Court concluded that Congress did not intend the "general acceptance" standard to be applied as the sole test of admissibility.

Having determined that *Frye* no longer applied to litigation in the federal system, the Court declared that Rule 702 establishes a "gatekeeping" role for the federal trial courts, obligating the judge to "ensure that any and all scientific testimony or evidence is not only relevant, but reliable."

As to reliability, the Court noted that Rule 702 required that an expert's testimony be "scientific knowledge," a term that implies a grounding in the procedures of science. "Knowledge" implies that the proposition must constitute more than subjective belief or unsupported speculation. Together, the two terms mean that experts must derive their assertions by means of the scientific method.

As to relevancy, the Court also looked to the language of Rule 702, noting that the rule requires that the scientific evidence assist the trier of fact. To be admissible, the evidence must "fit" the factual dispute. "Fit" is not always obvious, the Court explained, as scientific validity for one purpose does not necessarily constitute scientific validity for another. But there must be a scientific connection between the testimony and the pertinent inquiry.

To help the trial courts determine whether evidence constitutes scientific knowledge that will assist the trier of fact, the Court articulated the following nonexhaustive list of factors: (1) whether the theory or technique can be and has been tested; (2) whether it has been subjected to peer review and publication; (3) the known or potential rate of error, (4) the existence and maintenance of control standards; and (5) whether the theory or technique enjoys general acceptance in the relevant scientific community. The Court specifically admonished trial judges to focus on experts' methodologies, not their conclusions, when applying these factors.

The Court further reminded the trial judges that they must consider a host of other evidentiary rules—for example, Rule 403, which permits the exclusion of relevant evidence if its probative value is substantially outweighed by the "danger of unfair prejudice, confusion of the issue, or misleading of the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." The Court also commented on the strength of the adversary system, noting that cross-examination and the introduction of contrary evidence are powerful tools to combat shaky evidence. Trial judges remain free, the Court advised, to grant summary disposition if the evidence is insufficient to support a jury verdict upholding the proffered position.

Finally, the Court conceded that important differences exist between the search for truth in the laboratory and the search for truth in the courtroom. The former involves a perpetual revision where wrong or incomplete answers prove useful to the

---

20. *See* Daniel J. Capra, *The Daubert Puzzle,* 32 GA. L. REV. 699, 701 (1998). For a concise overview of the history of *Daubert* and a broad discussion of its application in toxic tort cases, *see* Christopher H. Buckley Jr. & Charles H. Haake, *Separating the Scientists Wheat from the Charlatan's Chaff: Daubert's Role in Toxic Tort Litigation,* 28 ENVTL. L. REP. 10,293 (1998).

quest for an ultimate truth, while the latter involves reaching a quick, final solution about a given set of facts. Because of these differences, the Court admitted that judges inevitably will prevent the jury from hearing about certain innovations that may turn out to be correct. That event, however, is the balance struck by the rules, which are "designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes."

B. Joiner

Four and a half years after *Daubert*, the Court reaffirmed trial judges' gatekeeper functions in *Joiner*. The primary issue in that case was what standard appellate courts should apply when reviewing district court determinations of admissibility. The 11th Circuit, applying what was described as a "particularly stringent standard of review," reversed the trial court's decision to exclude the plaintiff's scientific evidence and grant summary judgment to the defendant. The Supreme Court in turn reversed, holding that abuse of discretion constituted the appropriate standard of review.

Applying that standard, the Court concluded that the trial court did not abuse its discretion, but rather was within its discretion in excluding the plaintiffs scientific expert testimony because the animal and epidemiological studies on which that testimony was based did not reliably support the conclusions drawn. Conclusions and methodology are not entirely distinct from one another, the Court stated, continuing:

> [N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.[21]

C. Putting It All Together

The Court's decision in *Daubert* ushered in a new regime under which the federal courts analyze the admissibility of scientific expert testimony. The decision itself has raised a myriad of questions concerning the proper performance of the gatekeeping role, and the Court's subsequent decisions and opinions in *Joiner* and *Kuhmo Tire* only scratch the surface in answering those questions. In large part, the Court seems to have remained purposefully vague. Despite the confusion and ambiguity, however, a general framework can be drawn.

First, *Daubert* strengthens the trial court's role in assessing scientific evidence. Although *Daubert* enables district courts to admit a somewhat broader range of scientific testimony than was possible under *Frye*, trial judges nonetheless possesses wide discretion to sift through experts' attestations.[22] They do not have to defer to the scientific community when making admissibility determinations. Instead, they play an active part in vigorously ferreting out expert opinion not based on relevant scientific methodology.[23]

Second, trial judges are to analyze reliability at every stage of the expert's decision-making process. The court must consider not only whether each step of the underlying methodology is reliable, but also whether the conclusions drawn from the methodology are reliable. If the methodology is flawed at any step, then the testimony does not meet the standard for admissibility under Rule 702.[24] "This is true whether the step completely changes a reliable methodology or merely misapplies that methodology."[25]

---

21. 118 S.Ct. at 519.

22. See Zuchowicz v. United States, 140 F.3d 381, 386 (2d Cir. 1998) (discussing trial court's strengthened role).

23. Cavallo, 892 F.Supp. at 774.

24. *See* Hall v. Baxter Healthcare Corp., 947 F.Supp. 1387, 1401 (D. Or. 1996) (court performing gatekeeping role must ensure faithful application of scientific methodology "from initial premise to ultimate conclusion" and not admit evidence based only on "leap of faith").

25. Paoli, 35 F.3d at 745.

Third, the trial court must consider the fit of both the scientific technique and the conclusion drawn therefrom to the actual issues in dispute in the case. The final conclusions formed by experts must connect the science to the issues before the factfinder. The exact standard for fit remains somewhat elusive, but courts agree that it is a higher standard than the general relevancy requirement of Rule 402.[26]

Here the reliability and relevance analyses overlap. If the underlying methodology is not reliable, or if the conclusions do not reliably flow from valid methodology, then the testimony does not meet *Daubert's* fit requirement. As the Court indicated in *Joiner,* sometimes "there is simply too great an analytical gap between the data and the opinion proffered."[27] Therefore, the standard for fit requires a sound conclusion, based on valid scientific procedures, that clearly affects the resolution of a contested issue. Consequently, the standard for fit looks more like an analysis of sufficiency than admissibility.

Finally, trial judges must apply other provisions of the Federal Rules of Evidence, particularly Rule 403. *Daubert* makes clear that the requirements for admissibility under Rule 702 do not foreclose the applicability of other rules, particularly Rule 403.

DIFFERENTIAL DIAGNOSIS AND ADMISSIBILITY

Post-*Daubert* cases addressing the admissibility of causation testimony based on differential diagnosis have split into three basic camps.

A. Overview of the Cases

1. "Broad Admissibility" Approach

These decisions share the common characteristic of allowing physicians to testify as to both levels of causation based exclusively on their use of differential diagnosis. In *McCullock v. H.B. Fuller Co.,* for example, the Second Circuit affirmed the admission of testimony that fumes from glue caused the plaintiff's throat polyps, even though the physician could point to no medical literature identifying glue fumes as a general causal agent of the injury.[28] The doctor's opinion passed muster under *Daubert* because it was based on differential diagnosis, and the trial court therefore did not abuse its discretion in admitting the testimony. Any faults with the use of this technique as a methodology went to weight, rather than admissibility.

Federal district courts in Louisiana and Colorado also have allowed medical expert testimony on the issue of general causation derived solely from differential diagnosis.[29]

Because differential diagnosis constitutes the primary clinical tool by which medical doctors determine the disease from which a patient suffers, as well as the possible etiologic agents of that disease, the "broad admissibility" approach allows it as evidence of either level of causation. In short, "broad admissibility" requires only that the physician employ in the courtroom the same techniques used when treating patients in the examination room.

2. "Middle Ground" Approach

These decisions often admit causation evidence derived from differential diagnosis, but they require that the clinical procedure be coupled with something more. In *Heller,* for example, the Third Circuit concluded that Dr. Papano's differential diagnosis evidence satisfied *Daubert's* reliability prong, even though he relied on no published studies linking the chemicals in the carpeting to the type of respiratory problems from which Heller suffered. The

---

26. *See* Daubert on remand, 43 F.3d 1311, 1321 n.17 (9th Cir. 1995); Paoli, 35 F.3d at 745.

27. 118 S.Ct. at 519.

28. 61 F.3d 1038, 1043 (2d Cir. 1995).

29. Pick v. Am. Med. Sys. Inc., 958 F.Supp. 1151, 1162-63 (E.D. La. 1997); Wilson v. Petroleum Wholesale Inc., 904 F.Supp. 1188, 1190 (D. Colo. 1995).

court affirmed the exclusion of the testimony, however, because the temporal relationship used by the doctor did not support a conclusion that the carpet caused the plaintiffs illness. Heller's symptoms first appeared several weeks after the installation of the carpet, and they continued after the carpet was removed.

As *Heller* demonstrates, the "middle ground" cases allow differential diagnosis evidence as long as the physician also relies on some fact or circumstance indicative of general causation. This additional proof usually takes the form of a close temporal relationship between the plaintiff's exposure to a supposedly toxic substance and the onset of illness or injuries.[30] Alternately, this proof might consist of generalized allegations, derived from anecdotal evidence but unsupported by any scientific study, that the scientific community possesses wide knowledge of the presumed causal agent's harmful effects.[31]

In either situation, the court apparently views this additional proof as bolstering the doctor's clinical determination that exposure to the suspected product resulted in the plaintiff's illness. Such evidence presumably allows the doctor to include the product in the list of possible etiologic agents. Put differently, a close temporal link between exposure and symptom, or an unsupported but widely circulated belief, provides a reliable basis for the assumption that the product is capable of causing the disease in question. Without such evidence, no reliable basis exists, and the opinion must be excluded.

Under the "middle ground" approach, therefore, medical experts bear some burden to show why they considered the defendant's product to be a potential cause in the first place. Some cases suggest a different presumption, however, viewing differential diagnosis as inherently reliable unless the defendants offer plausible alternative causes of the illness and the experts fail to explain why their conclusions remain valid.[32]

3. "Narrow Admissibility" Approach

The third group of decisions, like the second, requires the expert to "rule in" the defendant's product. The "narrow admissibility" approach, however, does not consider reliance on temporality or anecdotal evidence to be a valid method of doing so. Rather, these cases demand "hard science" on the issue of general causation, such as published and peer-reviewed scientific studies establishing a statistically significant link between the substance and the disease.

The Fifth Circuit's en banc decision in *Moore v. Ashland Chemical Inc.* provides a good example.[33] The court affirmed the district judge's exclusion of medical testimony based on differential diagnosis, a temporal relationship and the manufacturer's material safety data sheet containing generalized statements about the potentially harmful effects of its chemical. Although the majority referred only to the physician's "examination and test results," the dissent makes clear that the doctor performed a differential diagnosis. The doctor

30. *See, e.g.,* Zuchowicz, 140 F.2d at 385 (explaining that expert reached conclusion on causation after considering temporal relationship and conducting differential etiology).

31. *See, e.g.*. Kannankeril v. Terminix Int'l Inc., 128 F.3d 802, 809 (3d Cir. 1997) (as amended) (finding that "widely accepted scientific knowledge of the harmful nature of organophosphates" bolstered expert's conclusion). In the original opinion in *Kannankeril*, the court declared: "It is an acknowledged scientific fact that chlorpyrifos, the active ingredient in Dursban, is harmful to humans and can cause the very symptoms displayed by Dr. Kannankeril." No. 96-5818, slip op. at 12 n.8 (3d Cir. Oct. 17, 1997). The court cited no authority for its proposition. In the amended version, the court deleted this sentence and referred to a letter written by one of the experts summarizing various reports on organophoshates generally, but none on chlorpyrifos specifically.

32. Kannankeril, 128 F.3d at 808. This presumption seems unjustifiably to shift the burden of proof to the defendant.

33. 151 F. 3d 269 (5th Cir. 1998) (en banc).

could not point to any reliable studies connecting the chemical to the plaintiff's injury at the relevant exposure level, however, and this lack of tested and peer-reviewed literature constituted the fatal flaw in his opinion.

B. Application of the Daubert Framework

Experts can attempt to explain three distinct aspects of causation by providing differential diagnosis evidence (1) that the defendant's product is capable of causing the disease from which the plaintiff suffers, (2) that the product indeed caused that disease in this plaintiff, and (3) that other agents did not cause the plaintiff's disease. The first aspect obviously implicates the element of general causation, while the second and third concern specific causation. Because each of these aspects affects a different element of the causation issue, the admissibility of differential diagnosis testimony as to each element deserves separate treatment.

1. General Causation

Testimony based on differential diagnosis is never admissible with regard to whether a certain substance can generally cause the disease in question because it fails to satisfy both the reliability and relevance requirements of *Daubert.*[34] Taking relevance first, differential diagnosis at best addresses only the issue of specific causation.[35] It does not seek to establish causal links between the remaining substances and the disease in the general population, and it therefore does not fit the general causation issue.

For this same reason, differential diagnosis does not satisfy *Daubert's* reliability requirement. Differential diagnosis presumes, but does not itself establish, that the substance in question is capable of producing the harmful effects. Presumption and supposition simply do not satisfy the rigors of the scientific method. Differential diagnosis does not, of itself, "rule in" any causal agent.

It fails, moreover, to satisfy the *Daubert* factors in the general causation context: (1) it has not been peer reviewed as a method of establishing general causation; (2) no publications exist describing it as such; and (3) epidemiologists and toxicologists, those scientists who study the causes of disease, do not employ it as a methodology of their disciplines.[36]

This is not to say that physicians may never testify on the issue of general causation. To do so, however, they must have done something more than rule out other potential causes. Rather, they must explain how they were able to "rule in" the product in question. Put differently, they must point to some reliable evidence on general causation, employing the principles and methods of epidemiologists or toxicologists, before giving an opinion relating to those fields.[37] Having consulted scientific studies with the qualifications necessary to explain the methodologies used and extrapolated the data to the instant case, physician experts may testify that the product can cause the disease.[38]

Physicians must consult and rely on "hard science" before offering opinions on general causation. Because the "broad ad-

---

34. Breast Implant, 11 F.Supp.2d at 1230.
35. Cavallo, 892 F.Supp. at 771.
36. Patricia E. Lin, Note, *Opening the Gates to Scientific Evidence in Toxic Exposure Cases: Medical Monitoring and Daubert*, 17 REV. LITIG. 551, 575-80 (1998).
37. *See* Cavallo, 892 F.Supp. at 771 (although physician was not toxicologist, he nonetheless must apply principles and methods of toxicology to give opinion on issue relating to that specialty).
38. *See, e.g.,* Baker v. Dalkon Shield Claimants Trust, 156 F.3d 248, 252-53 (1st Cir. 1998) (testimony reliable where physician not only performed differential diagnosis but referred to scientific studies supporting his theory); Glaser v. Thompson Med. Co., 32 F.3d 969, 975-78 (6th Cir. 1994) (doctor had conducted differential diagnosis and authored published studies relating to general causation); Lakie v. SmithKline Beecham, 965 F.Supp. 49, 55-57 (D. D.C. 1997) (admitting testimony where doctors employed differential diagnosis and consulted studies showing causal link between chemical and closely related disease).

missibility" approach allows a physician's general causation testimony based solely on differential diagnosis, that approach does not faithfully apply the *Daubert* framework. Instead of requiring scientifically valid methodologies relating to general causation—such as dose-response and epidemiological and toxicological studies—"broad admissibility" permits experts to opine based on assumption, thereby ignoring the purpose of *Daubert's* gatekeeping obligation.

The justification for the "broad admissibility" approach is the wide use of differential diagnosis in clinical medicine. The response is found in *Daubert*, which acknowledges the "important differences between the quest for truth in the courtroom and the quest for truth in the laboratory."[39] In medicine, physicians assume the most likely causal agent of their patients' illnesses so as to prescribe treatment and relieve suffering. As the maxim goes, medicine is not an exact science; it often proceeds by trial and error.

Law is not an exact science either, but it has developed certain rules to help ensure that allegedly wronged persons receive compensation only from those who wronged them. One of the oldest of these rules is the requirement that the defendant's conduct actually caused the harm. Courts primarily need expert evidence demonstrating that the product is capable of causing the harm. Courts should not expect more from experts than the level of intellectual rigor found in the relevant field. For purposes of general causation, the relevant field is epidemiology or toxicology, not clinical medicine. Clinical techniques like differential diagnosis do not bear on general causation and are inadmissible as to that issue.

Similarly, to the extent it permits testimony on the issue of general causation, the "middle ground" approach fails to apply the *Daubert* framework faithfully. Permitting physician experts to "rule in" the defendant's product based on nothing more than a close temporal relationship and generalized allegations proves no more valid than allowing them simply to assume the product can cause the disease. The conclusion still rests on conjecture. Temporality and case studies may give rise to a hypothesis regarding general causation, but they certainly do not provide proof in support of that hypothesis.

The "narrow admissibility" approach, which requires the physician expert to consult and extrapolate from scientific studies, comes closest to the correct *Daubert* analysis of this question.

2. Specific Causation

In contrast to its use as proof of general causation, differential diagnosis is ordinarily admissible with regard to both aspects of specific causation. Concerning what did not cause the plaintiff's injury, differential diagnosis is both reliable and relevant. After all, physicians use the technique as a way of ruling out potential causes of symptoms. Differential diagnosis also satisfies many of the *Daubert* factors when used for this purpose: (1) it has been peer reviewed and tested; (2) books have been published explaining the process; and (3) it enjoys general acceptance in the medical community.

Finally, when proffered to rule out alternative causes, differential diagnosis fits a disputed issue in the case. Plaintiffs must be able to eliminate, or at least minimize, the chance that other etiologic agents contributed to the injury in order to prove that the defendant's product more likely than not caused the disease.[40]

Even though differential diagnosis satisfies *Daubert* when utilized to eliminate alternative causes, courts should scrutinize physicians' testimony carefully for the potential to mislead and confuse. A jury can easily misinterpret evidence regarding

---

39. 509 U.S. at 596-97 (1993). *See also* Breast Implant, 11 F.Supp.2d at 1230 (recognizing distinction between causation in clinical sense and causation in legal sense).

40. Cavallo, 892 F.Supp. at 771.

what did not cause an injury as evidence of what did, especially when it comes from a well-credentialed medical doctor. Courts must satisfy themselves that juries understand the purpose for which such evidence is proffered, and judges should consider the appropriateness of limiting instructions under Rule 105. If, however, the testimony has such great potential to misdirect and confuse that it cannot be cured by careful instruction, it must be excluded under Rule 403.

In addition to its admissibility as to what did not cause an injury, physicians' expert testimony based on differential diagnosis is admissible with regard to what did cause such injury. Again, when used for this purpose, the process meets both the reliability and relevance requirements of *Daubert.* A medical opinion as to a plaintiff's disease and its underlying etiology has relevance to the question of liability. While plaintiffs can produce hundreds of epidemiological studies showing a statistically significant correlation between the product and the disease, they must also prove that the product caused the disease in the instant case.

Medical testimony is the best way to meet this burden. Moreover, a specific causation opinion based on differential diagnosis fits the data collected—histories, examinations and observations relating to the illness of one particular individual.

To show that differential diagnosis is reliable when tendered for this purpose proves a bit trickier, primarily because of the ease with which admissibility can be confused with sufficiency. Looking at *Kumho Tire* again, it becomes clear that judges should hold a witness only to those standards that typify the practice of the relevant field. For purposes of general causation, the relevant field is epidemiology or toxicology. For purposes of specific causation, however, the focus shifts to clinical medicine because physicians, not toxicologists, treat individual patients. As part of that treatment, the physician to some extent must determine what is causing the patient's illness.

Here, differential diagnosis becomes reliable since it constitutes the standard diagnostic procedure by which physicians determine the appropriate disease and its most likely underlying causes. For purposes of explaining the cause of an individual plaintiff's injury to a reasonable degree of medical certainty, differential diagnosis remains valid science. Accordingly, it should be admissible for this purpose even when the physician fails to consult scientific studies that "rule in" the defendant's product

The "narrow admissibility" approach consequently seems to run afoul of *Daubert* in this regard by demanding that the expert consult "hard science" before offering a causation opinion. The decisions grouped in this category repeatedly refer to the necessity of ruling in the suspected cause and justifiably reject differential diagnosis for this purpose.[41] The courts' uneasiness with clinical evidence, unsupported by "hard science," is understandable, especially in light of *Joiner's* suggestion that gatekeeping involves winnowing out those opinions that require too great an analytical leap.[42] As a result, these decisions exclude the physician's testimony as unreliable.

Underlying the exclusions of physician testimony in the "narrow admissibility" cases, however, is the plaintiffs' complete failure to provide *any* reliable expert testimony concerning general causation. In *Cavallo,* for example, the plaintiff attempted to proffer the opinion of a toxicologist as well as her physician. The court first excluded the toxicologist's testimony on the issue of general causation because, to the extent his theory had been tested in the scientific literature, it failed. Hence, the testimony was neither scientifically valid nor admissible under *Daubert.* Only

41. *See, e.g.,* Nat'l Bank of Commerce v. Associated Milk Producers Inc., 22 F.Supp.2d 942, 963-67 (E.D. Ark. 1998); Breast Implant, 11 F.Supp.2d at 1229-30; Hall, 947 F.Supp. at 1413; Cavallo, 892 F.Supp. at 771-72.

42. Joiner, 118 S.Ct. at 519.

after excluding this general causation evidence did the court fault the physician's testimony as incapable of ruling in the defendant's product.

Had the toxicologist produced reliable general causation evidence, however, the court likely would have allowed the doctor to testify. The court's decision to exclude the differential diagnosis testimony, as well as its subsequent decision to grant the defendant's motion for summary judgment, had more to do with the sufficiency of that testimony to carry the plaintiff's case than with its admissibility.[43]

In the end, differential diagnosis evidence is admissible under *Daubert* when offered to establish specific causation, but a plaintiff still may lose the case on summary judgment because differential diagnosis is not sufficient to meet the burden of proof.

DIFFERENTIAL DIAGNOSIS AND SUFFICIENCY

Although *Daubert* ostensibly dealt only with the issue of admissibility, its fit requirement, as explained in *Joiner,* raises questions concerning its significance on the issue of sufficiency. The standard for fit requires a sound conclusion, based on scientifically valid procedures, that clearly and directly speaks to a disputed issue in the case. If the methodologies used by the expert are not reliable, or if the conclusion does not adequately flow from those methodologies, the court may exclude the testimony. As *Joiner* explained: "A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."[44] This statement, while directly addressing the admissibility of scientific evidence, in actuality appears to be a standard for determining whether the evidence is sufficient to meet the proffering party's burden of proof.

The lower courts disagree as to whether *Daubert*'s gatekeeping obligation altered the role judges play in determining sufficiency.[45] The Second Circuit, for example, concluded in *In re Joint Eastern and Southern District Asbestos Litigation* "that *Daubert* did not alter the traditional sufficiency standard."[46] Noting that admissibility and sufficiency "necessitate different inquiries and involve different stakes," the court held that the standard for sufficiency mirrors the standard for determining judgment as a matter of law. Thus, unlike the probing inquiry that characterizes judges' role as gatekeepers for purposes of admissibility, the appropriate standard for assessing sufficiency remains "whether a reasonable trier of fact could find in favor of the non-moving party."[47]

The Sixth Circuit employed a different approach in *Conde v. Velsicol Chemical Corp.,*[48] in which it affirmed summary judgment for the defendant. Although the plaintiffs contested the trial court's exclusion of their expert witnesses' testimony, the court stated that the real issue was the trial court's alternative determination that the expert testimony was insufficient to prove causation. The court then engaged in a *Daubert*-like analysis, finding various flaws in their methodologies and noting that the epidemiological studies on the subject found little evidence linking the supposed cause to the injury in question. Accordingly, their conclusions did not reliably flow from the data collected, and the trial court was right in finding the evidence insufficient on the issue of causation.[49]

---

43. 892 F.Supp. at 774-75.

44. 118 S.Ct at 519. Indeed, Joiner cited as authority the Sixth Circuit's opinion in Turpin v. Merrell Dow Pharm. Inc., 959 F.2d 1349, 1360 (6th Cir. 1992), *cert. denied,* 506 U.S. 826 (1992), a case dealing with sufficiency rather than admissibility.

45. *See generally* Capra, *supra* note 19, at 751-55 (discussing Daubert and the sufficiency inquiry).

46. 52 F.3d 1124, 1133 (2d Cir. 1995).

47. Capra, *supra* note 19, at 752.

48. 24 F.3d 809 (6th Cir. 1994).

49. *See also* Merrell Dow Pharm. Inc., v. Havner, 953 S.W.2d 706, 713 (Tex. 1997) (applying *Daubert* factors to sufficiency inquiry and stating that U.S. Supreme Court would agree that determination of scientific reliability is appropriate in reviewing legal sufficiency).

The debate over *Daubert's* application to the sufficiency inquiry is, according to one commentator, "more apparent than real . . . because admissibility and sufficiency often go hand in hand, especially in toxic tort cases, where exclusion of an expert on admissibility grounds is usually tantamount to a dismissal on insufficiency grounds."[50] That is certainly true of the "narrow admissibility" decisions described above, many of which excluded differential diagnosis evidence because the conclusion that the defendant's product caused the plaintiff's injury required too great an analytical leap in the absence of reliable general causation evidence. Put differently, the evidence did not fit the data.

While *Daubert* clearly allows a court to make this type of ruling under the rubric of admissibility, the real issue in these situations is the plaintiff's ability to satisfy the burden of production. Therefore, under either the Second Circuit's traditional approach to sufficiency or the Sixth Circuit's heightened analysis, differential diagnosis is never sufficient to send the case to the jury. Differential diagnosis has only limited admissibility; it can be used only to establish specific causation.

Differential diagnosis never satisfies *Daubert* so as to be admissible on the issue of general causation. When plaintiffs cannot offer any scientifically valid evidence concerning a product's general ability to cause the injury in question, they fail to make out a prima facie case, and summary judgment is warranted even if plaintiffs offer admissible medical testimony concerning specific causation.

Hence, the "narrow admissibility" decisions confuse the issues, but they ultimately reach the right result—summary disposition based on a failure to produce reliable proof that the product can cause the disease.

CONCLUSION

Daubert dramatically changed the system for testing the admissibility of scientific evidence. As a result, it changed the way in which toxic and mass tort cases are litigated. Because plaintiffs must have expert testimony concerning both general and specific causation, the admissibility and sufficiency of that testimony becomes crucial. A decision that the expert testimony does not meet the standards for reliability or fit renders plaintiffs incapable of proving all the elements of their claims. Likewise, even when courts admit expert testimony, plaintiffs lose if the evidence does not suffice to prove that the defendant's product more likely then not caused the injuries.

One of the sources of expert testimony frequently used to establish causation in mass and toxic tort cases is the medical process known as differential diagnosis. Because this technique collects data relating to a particular patient, it is never admissible under *Daubert* with regard to general causation. Not only does differential diagnosis, by focusing on individuals, not fit the issue of general causation, it also fails *Daubert*'s reliability prong by assuming, rather than proving, that the supposed cause actually produces the disease in question. Accordingly, courts that adhere to the "broad admissibility" approach, which allows expert medical testimony as to either level of causation, do not faithfully fulfill their gatekeeping obligation.

The "middle ground" approach, which permits a physician to "rule in" the suspected product based on temporality or anecdotal evidence, similarly falls short. Epidemiology and toxicology constitute the relevant scientific fields when proving general causation, and a medical doctor must employ the methodologies of those disciplines to opine on the general causation issue.

The "narrow admissibility" approach comes closest to the appropriate analysis under *Daubert* by demanding that the physician consult "hard science" in the form

50. Capra, *supra* note 19, at 754.

of tested studies. But this approach overlooks the distinction between general and specific causation. Because clinical medicine constitutes the relevant field of study as to the latter, testimony based on a properly performed differential diagnosis satisfies *Daubert* with regard to specific causation. The physician should be allowed to give an opinion concerning what did cause the illness as well as what did not.

Courts should examine such testimony carefully under Rule 403, however, to make sure that it does not mislead or confuse the jury. In the end, though, differential diagnosis evidence generally remains admissible on the issue of specific causation, and to the extent that it excludes differential diagnosis in this context, the "narrow admissibility" approach reaches further than it should.

Although *Daubert* seems to provide for such a result by allowing the district courts to conclude that the analytical gap between the data and the ultimate opinion is simply too great, the Supreme Court would have done better to classify this as an assessment of sufficiency rather than admissibility. Indeed, the Court itself lifted that standard from a lower court decision addressing sufficiency. Moreover, the application of *Daubert* often leads to the exclusion of evidence that should be admissible when the two inquiries are theoretically separated, but that requires the fact finder to engage in too much speculation or conjecture. Differential diagnosis falls into this description.

Courts should allow physician expert testimony based on differential diagnosis but unsupported by "hard science" when proffered to establish specific causation. But if plaintiffs cannot independently demonstrate general causation by scientific studies, then they fail to make out a prima facie case, and summary judgment should be granted to defendants.

Until the Supreme Court concedes that *Daubert* affects sufficiency review, however, lower courts will likely continue to confuse that inquiry with the assessment of admissibility. Of course, that concession necessarily implicates substantive tort policy, an area governed by state law. Such a concession therefore would involve *Erie Railroad Co. v. Tompkins,*[51] begging the question whether *Daubert* remains valid in light of that decision's federalism concerns.

---

51. 304 U.S. 64 (1938).